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| 10/577,379 | 04/28/2006 | Hiroynki Sato | 2006-0613A | 6851 |
| 513 7590 10/10/2008 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021 | | | EXAMINER BOYKIN, TERRESSA M | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/577,379

Applicant(s)

SATO ET AL.

Examiner

Terressa M. Boykin

Art Unit

1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-14 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
3) ☐ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

Response to Amendment

Applicant's arguments with respect to claims 1-14 have been considered but are moot in view of the new ground(s) of rejection. Nevertheless, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., moisture content, acid values, impurity content, level of proton-source impurities etc.) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 112

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the proton does not reasonably provide enablement for any type or amount of proton source. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make any use the invention commensurate in scope with these claims.

Note, applicant's specification states on pages 12 line 27 through 13 line 1 that the total proton concentration of the impurities contained in the cyclic ester is preferably 0.01 to 0.5 mol% appears to be necessary in order for the process to be successful. Further, the only carboxyl group-capped agents described are similar in structure and are included on page 19 of the specification. There are no examples or evidence the resulting product would have the characteristics to which applicants are claiming when these two moieties, i.e. total proton conc. of mol% impurities.

Case law holds that applicant's specification must be "commensurately enabling [regarding the scope of the claims]." See *Ex Parte Kung*, 17 USPQ2d 1545, 1547 (Bd. Pat. Appl. Inter. 1990). Otherwise **undue experimentation** would be involved in determining how to practice and use applicant's invention. The test for undue experimentation as to whether or not all compounds within the scope of claims 1-14 can be used as claimed and whether claims 1-112 meet the test is stated in *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. Appl. Inter. 1986) and *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Upon applying this test to claims ***, it is believed that undue experimentation **would** be required because:

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(a) *The quantity of experimentation necessary* is **great** since claims 1-14 read on any type of proton source having a concentration exceeding that which is disclosed by the specification.

(c) *There is an **absence** of working examples concerning making the aliphatic polyester having the specific resulting characteristics comprising any type of proton source impurities other than those disclosed in the specification, i.e. the total proton concentration of the impurities contained in the cyclic ester is preferably 0.01 to 0.5 mol% and carboxyl end capping agent other than mono and poly-carbodiimide, oxazolines, oxazines and epoxy compounds.*

In light of the above factors, it is seen that undue experimentation would be necessary to make and use the invention of claims 1-14.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.

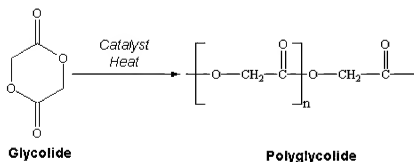
102 that form the basis for the rejections under this section made in this

Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1048683 see pages 1-81 and paragraphs as designated below.

The Examiner first notes that the it is commonly known which will be demonstrated below to produce an aliphatic polyester particularly polyglycolic acid from glycolide



The Examiner also notes that it appears that the crux of the invention in view of the specification is that, in the presence of water the polyglycolide is unstable. It appears to the examiner that applicants have attempted to stabilize the polyglycolide by adding end capping agents such as those claimed affording a more stable polymer even under hydrolytic conditions.

The instability of the polyester is well known and addressed in the art and the positive aspects due to its degradability and thus useful in the biomedical field of the polyester is also well known.

Thus, **with regard to applicants' claims 1 and 2** which is directed to a process for producing an aliphatic polyester, comprising: subjecting a cyclic ester containing water in excess of 80 ppm as an initiator or/and a molecular weight-adjusting agent to ring-opening polymerization based on a total proton concentration in the cyclic ester as an index, and compounding a resultant aliphatic polyester with a carboxyl group-capping agent which may be an epoxy compound.

The reference **EP 1048683** addresses the problem and/or advantage of biodegradation like applicants by adding an agent such as those disclosed. For example in **EP1048683** discloses aliphatic polyesters which are composed of at least one kind of monomer unit of any one of a lactone or lactide composition. [0069]. The aliphatic polyester contains a bond as shown above which allows reaction between it and a modifying agent such as a n alcohol terminal moiety or a carboxylic acid terminal moiety.

Note for example in paragraph [00187] that a monoepoxy compound may be employed for capping the terminals of the polymer chain.

Note also for example in [00468] that diethylene glycol was used as an initiator with octylate catalyst are added to caprolactone monomer having a water content of 150ppm and an acid value of .10 mg-KOH/g and a lactide monomer having a water content of 70ppm and an acid value of .12 mg-KOH/g to prepare a caprolactone/lactide block copolymer, a proportion of the moiety has an alcohol terminal and a carboxylic terminal of 63% and 37% respectively. the lactide was polymerized after polymerization of caprolactone. Note also that catalyst are employed that may be metal compounds such as Al, Ti, Sn and Zn including metal oxides although not limited thereto. See also paragraphs [0175] - [0206].

With regard to claims 7 and 8 note that the reference discloses that the cyclic ester monomer can be polymerized by ring opening through continuously supply the cyclic ester monomer in to a continuous melt-polymerization apparatus. The apparatus may be a column type reactor and may be employed in combination of two or more kinds which would anticipate applicants "plurality of tubes". See [0200] –[0202]

Claims 1-6 and 9-11 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0299730 see abstract and claims 1-6.

EP 0299730 discloses on pages 1-2 and claims a lactide and a glycolide which are copolymerized to prepare a dilactic acid glycolic acid copolymer. the polymerization is performed in the presence of a regulator which is alpha hydroxy lower fatty acid containing water and in the amount of .25 to 50wt. % based on the sum of the lactide and the glycolide. The catalyst is stannous octoate. The process consist of copolymerizing lactide and glycolide using a regulator which may be alpha hydroxy lower fatty acid such as glycolic acid and water. The amounts as disclosed in the

abstract and in claims appear anticipate those amounts as disclosed. Note that the reference discloses the use of a polymerization regulator which may anticipate the molecular weight adjuster as claimed by applicants.

Thus, each of the references **EP 1048683** or **EP 0299730** discloses a ring-opening polymerization reaction to produce a polyester prepared from the same components as claimed by applicants. Since the disclosed amounts of water in ppm are expressed differently and thus may be distinct from those claimed, it is incumbent upon applicant(s) to establish that they are in fact different and whether such difference is unobvious. In view of the above, there appears to be no significant difference between the reference(s) and that which is claimed by applicant(s). Any differences not specifically mentioned appear to be conventional. Consequently, the claimed invention cannot be deemed as novel and accordingly is unpatentable.

Claim Rejections - 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis or all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12 and 13 rejected under 35 U.S.C. 103(a) as being unpatentable over either EP 1048683 or EP 0299730 in view of USP 5885709 or 2937164 see abstract, claims.

With regard to applicants' claims 12 and 13 wherein the carboxyl group-capping agent is selected from the group consisting of monocarbodiimide, polycarbodiimides, oxazolines, and oxazines and epoxy compounds.

Both the **EP 1048683** and the **EP 0299730** reference discloses a ring opening polymerization of an aliphatic polyester by the process as claimed except for specifying the particular end capping agent as claimed other than an epoxy moiety. The end capping agents listed in claim 12 are well-known in the art and particularly with regard to claim 13, monocarbodiimide is a well known end capping agent for polyesters.

For example, **USP 5885709** discloses a polyester which may be reacted with carbodiimides, as capped carboxyl end groups, the carboxyl end groups being predominantly capped by reaction with mono- and/or biscarbodiimides which are present in the fibers and filaments in an amount of from 30 to 200 ppm, based on the weight of the polyester, the free carboxyl end group content being less than 3 meq/kg of polyester, and the fibers and filaments additionally containing at least 0.02 percent by weight of at least one free polycarbodiimide or of a reaction product containing still reactive carbodiimide groups, and also a process for the preparation thereof.

Note also **USP 2937164** discloses cross-linked polymer compositions and methods for their preparation and more specifically to cross-linked products resulting from the reaction between linear organic acid containing polymers :and monocarbodiimides and

the method of preparing the 20 cross-linked polymers. The term "monocarbodiinide" as used herein includes compounds having one carbodiimide group corresponding to the general formula $R-N=C--N-R'$ in which R and R' are alkyl, substituted alkyl, alkenyl, aryl, aralkyl, 25 alkyl aryl and substituted aryl.

Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the particular end capping agent as disclosed in either **USP 2937164** or **USP 5885709** since both reference discloses the benefits of employing the particular agent as a economically useful and rapidly processable reaction. One would have been motivated to use the end capping agent since both **EP 1048683** or **EP 0299730** discloses that the end capping agent affords a more stable and regulatable polyester.

Provisional Obviousness-type Double Patenting

The applicants have stated in response to the previous rejection:

The Examiner has provisionally rejected claims 1-14 for obviousness-type double patenting based on claims 1-12 of Serial No. 10/575,468. The Examiner is kindly requested to hold this rejection in abeyance pending an indication that the claims of the present application are otherwise in condition for allowance.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-12 of copending Application No. **10575468**. Note that the claims of the application although stated differently convey and contain therein the same limitations as that of the present application. Note claim 1 for examples also discloses a process for producing an aliphatic polyesters by subjecting the cyclic ester containing water and an initiator. the application is specific with regard to the initiator in stating that it is an alcohol. the claims also stress that a molecular weight adjusting agent to ring-opening polymerization based on the total proton concentration is claimed.

This is a provisional obviousness-type double patenting rejection since the conflicting claims have not yet been patented.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terressa M. Boykin whose telephone number is 571 272-1069. The examiner can normally be reached on Monday-Thursday 10-5:30 Friday (work at home).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Terressa M. Boykin/
Primary Examiner, Art Unit 1796

